UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, *et al.*,

Plaintiffs,

- against -

MARGARET HAMBURG, Commissioner of Food and Drugs, *et al.*

Defendants.

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MEMORANDUM & ORDER

No. 12-CV-763 (ERK)(VVP)

KORMAN, J.:

I. OVERVIEW

Plan B and Plan B One-Step are emergency contraceptives that can be taken to reduce the risk of pregnancy after unprotected intercourse. In 1999, Plan B became the first emergency contraceptive drug approved for prescription-only use in the United States. In 2006, the Food and Drug Administration ("FDA") approved non-prescription access to Plan B for women 18 and older, and with a prescription to adolescents under the age of 18. Subsequently, the FDA was ordered to make it available without a prescription to adolescents aged 17. *Tummino v. Torti*, 603 F. Supp. 2d 519 (E.D.N.Y. 2009). Even for women 17 and older, Plan B can only be purchased at a pharmacy and requires government-issued proof of age. Plan B One-Step was approved by the FDA in 2009 and is available without a prescription subject to the same restrictions. Though Plan B itself is no longer marketed, generic versions are available.

Both contraceptives contain the same total dose of levonorgestrel, a synthetic hormone similar to the naturally occurring hormone progesterone; Plan B consists of two pills containing 0.75 mg each of levonorgestrel that are to be taken 12 hours apart, while Plan B One-Step

consists of one pill containing 1.5 mg of levonorgestrel. Studies have shown that combining the two 0.75 mg doses of the hormone into one pill does not decrease its effectiveness; indeed, the two Plan B pills may be taken simultaneously, fewer than 12 hours apart, or up to 24 hours apart, without any adverse consequences. Both Plan B and Plan B One-Step are most effective when taken immediately after intercourse and preferably no later than 24 hours later, though they may retain some effectiveness if taken within 72 hours. Neither drug has any known serious or long-term side effects, though they may have some mild short-term side effects, such as nausea, fatigue, and headache.

Levonorgestrel-based emergency contraception "interferes with prefertilization events. It reduces the number of sperm cells in the uterine cavity, immobilizes sperm, and impedes further passage of sperm cells into the uterine cavity. In addition, levonorgestrel has the capacity to delay or prevent ovulation from occurring." U.S. Gov't Accountability Office, GAO-06-109, *Food and Drug Administration: Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual* at 12 (November 2005), Case No. 05-cv-366, Doc. No. 68-2 (hereinafter "GAO Report").[1] These contraceptives "have not been shown to cause a postfertilization event—a change in the uterus that could interfere with implantation of a fertilized egg." *Id.* at 13. Indeed, Diana Blithe, the biochemist who supervises research on contraception at the National Institutes of Health ("NIH"), opined that the possibility of levonorgestrel-based emergency contraceptives having an effect on implantation of fertilized eggs should "definitely" be taken off the labels for those drugs. Pam

[1] Citing H.B. Croxatto et al., *Mechanism of Action of Hormonal Preparations Used for Emergency Contraception: A Review of the Literature*, 63 Contraception, 111 (2001); H.B. Croxatto et al., *Pituitary-Ovarian Function Following the Standard Levonorgestrel Emergency Contraceptive Dose or a Single 0.75-mg Dose Given on the Days Preceding Ovulation*, 70 Contraception 442 (2004); A.L. Muller et al., *Postcoital Treatment with Levonorgestrel Does Not Disrupt Postfertilization Events in the Rat*, 67 Contraception 415 (2003); H.B. Croxatto et al., *Mechanisms of Action of Emergency Contraception*, 68 Steroids 1095 (2003).

Belluck, *Abortion Qualms on Morning-After Pill May Be Unfounded*, N.Y. Times, June 6, 2012, at A1. Consistent with this position, the NIH removed statements regarding emergency contraception's possible effect on implantation from its website. *Id.* Nevertheless, because it would be "unethical and logistically difficult to conduct the necessary research" to conclusively establish that levonorgestrel-based contraceptives do not interfere with implantation, "the possibility of a postfertilization event cannot be ruled out." GAO Report at 13. Presumably for this reason, the FDA-approved label for Plan B and its generic equivalents still suggests, without affirmative evidence, that "Plan B may also work by preventing fertilization of an egg . . . or by preventing attachment (implantation) to the uterus (womb)."

Plaintiffs in this case—organizations and individuals concerned with women's health, as well as minors and their parents—seek to expand the availability of Plan B and all emergency contraceptives. This action was originally brought in January 2005 to challenge the FDA's denial of a Citizen Petition seeking over-the-counter ("OTC") access to Plan B for women of all ages. The complaint asserted that the FDA's denial of the Citizen Petition, which it considered along with a number of proposals regarding over-the-counter access to emergency contraception submitted by Plan B's sponsor,[2] was arbitrary and capricious because it was not the result of reasoned and good faith agency decision-making. In a prior opinion, I concluded that the plaintiffs were right. *Tummino v. Torti*, 603 F. Supp. 2d 519 (E.D.N.Y. 2009).[3] In light of the overwhelming evidence of political pressure underlying the agency's actions, I vacated the

[2] Plan B was originally manufactured by Women's Capital Corporation, who later sold its right to market Plan B to Barr Pharmaceuticals, Inc. Barr was acquired by Teva Pharmaceuticals in 2008; Teva then took over the marketing of Plan B and developed the marketing for Plan B One-Step, which was approved by the FDA in 2009. For clarity I refer to these companies collectively as "Plan B's manufacturer," "the Plan B sponsor," or "the Plan B One-Step sponsor" although, as noted above, Plan B itself is no longer marketed.

[3] I also addressed and rejected the argument of the defendants that plaintiffs lacked standing. *Tummino*, 603 F. Supp. 2d at 539-542. I rejected this argument again when I denied the defendants' motion to dismiss in a hearing on April 27, 2012. Subsequently, the plaintiffs filed the current amended complaint, which adds as parties adolescents who are currently under 17 in place of those who aged out while the FDA dragged its heels in deciding the petition. I have nothing to add to my earlier discussion of this issue.

FDA's denial of the Citizen Petition and remanded for the agency to exercise its discretion without impermissible political intrusion. I also directed the FDA to make Plan B available to 17-year-old women without a prescription, because the same evidence relied on by the agency to support over-the-counter access to the drug by 18-year-olds applied equally to 17-year-olds—a holding which the FDA ultimately conceded was "consistent with the scientific findings [the FDA] made in 2005." FDA Statement, *Updated FDA Action on Plan B (levonorgestrel) Tablets* (Apr. 22, 2009).

The plaintiffs argued that the ultimate relief they sought—over-the-counter access regardless of age—should have been granted without a remand because "the agency has acted so improperly and in such bad faith that it cannot be trusted to conduct a fair assessment of the scientific evidence." Pls.' Reply Mem. in Supp. of Mot. for Summ. J. at 9, Case No. 05-cv-366, Doc. No. 257. I rejected this argument, although I agreed with the plaintiffs that the FDA bowed to political pressure emanating from the White House and departed from agency policy. I declined to grant the relief plaintiffs requested for two principal reasons. First, the Commissioner of the FDA had resigned and his replacement, as well as a new Deputy Commissioner, had been nominated by the newly elected President. This change in leadership suggested that the FDA could be "trusted to conduct a fair assessment of the scientific evidence." *Id.* Second, it was my view that the decision whether to make Plan B available without a prescription regardless of age was one that should be made by the FDA, to which Congress had entrusted the responsibility, and not by a federal district judge.

The FDA did not rule on the remanded Citizen Petition for almost three years. During this time, the agency again considered a proposal—referred to as a supplemental new drug application ("SNDA")—from Plan B's manufacturer; this proposal would have allowed over-

the-counter access to Plan B One-Step, the one-pill emergency contraceptive product, for all ages. The FDA agreed to approve this SNDA. FDA Commissioner Margaret Hamburg explained the process by which the FDA had reached its conclusion, with particular emphasis on the scientific evidence:

> The Center for Drug Evaluation and Research (CDER) completed its review of the Plan B One-Step application and laid out its scientific determination. CDER carefully considered whether younger females were able to understand how to use Plan B One-Step. Based on the information submitted to the agency, CDER determined that the product was safe and effective in adolescent females, that adolescent females understood the product was not for routine use, and that the product would not protect them against sexually transmitted diseases. Additionally, the data supported a finding that adolescent females could use Plan B One-Step properly without the intervention of a healthcare provider.
>
> It is our responsibility at FDA to approve drugs that are safe and effective for their intended use based on the scientific evidence. The review process used by CDER to analyze the data applied a risk/benefit assessment consistent with its standard drug review process. Our decision-making reflects a body of scientific findings, input from external scientific advisory committees, and data contained in the application that included studies designed specifically to address the regulatory standards for nonprescription drugs. CDER experts, including obstetrician/gynecologists and pediatricians, reviewed the totality of the data and agreed that it met the regulatory standard for a nonprescription drug and that Plan B One-Step should be approved for all females of child-bearing potential.

Statement from FDA Commissioner Margaret Hamburg, M.D., on Plan B One-Step (Dec. 7, 2011), Case No. 05-cv-366, Doc. No. 339-2. Commissioner Hamburg then observed that she had "reviewed and thoughtfully considered the data, clinical information, and analysis provided by CDER," and she expressly agreed that "there is adequate and reasonable, well-supported, and science-based evidence that Plan B One-Step is safe and effective and should be approved for nonprescription use for all females of child-bearing potential." *Id.*

Nevertheless, she explained that Kathleen Sebelius, the Secretary of Health and Human Services, "invoking her authority under the Federal Food, Drug, and Cosmetic Act to execute its provisions," disagreed with the agency's decision "to allow the marketing of Plan B One-Step

nonprescription for all females of child-bearing potential" and ordered Commissioner Hamburg to deny the Plan B One-Step SNDA. Secretary Sebelius explained that she had concluded "that the data submitted for this product do not establish that prescription dispensing requirements should be eliminated for all ages." Memorandum from Kathleen Sebelius, Sec'y Health and Human Servs., to Margaret Hamburg, Comm'r of Food and Drugs (Dec. 7, 2011), Case No. 05-cv-366, Doc. No. 339-1 (hereinafter "Sebelius Mem."). More specifically, she observed:

> The label comprehension and actual use studies submitted to FDA do not include data on all ages for which the drug would be approved and available over-the-counter. Yet, it is commonly understood that there are significant cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age, which I believe are relevant to making this determination as to non-prescription availability of this product for all ages. Although the average age of the onset of menses for girls in the United States is 12.4 years of age, about ten percent of girls reach menarche by 11.1 years of age. If the application is approved, the product would be available, without a prescription or other point-of-sale restrictions, even to the youngest girls of reproductive age.

Id. (citation omitted). The President endorsed this decision, explaining that "the reason [Secretary Sebelius] made this decision was she could not be confident that a 10-year-old or an 11-year-old go into a drugstore, should be able—alongside bubble gum or batteries—be able to buy a medication that potentially, if not used properly, could end up having an adverse effect." Statement by the President (Dec. 8, 2011), *available at* http://www.whitehouse.gov/the-press-office/2011/12/08/statement-president. The reader will observe that Secretary Sebelius did not say that, "if not used properly," levonorgestrel-based emergency contraception could have an "adverse effect" on the youngest girls of reproductive age, nor did she include within that group girls as young as 10. Indeed, the drug is currently available to the youngest girls of reproductive age with a prescription.

This case is not about the potential misuse of Plan B by 11-year-olds. These emergency contraceptives would be among the safest drugs sold over-the-counter, the number of 11-year-

olds using these drugs is likely to be miniscule, the FDA permits drugs that it has found to be unsafe for the pediatric population to be sold over-the-counter subject only to labeling restrictions, and its point-of-sale restriction on this safe drug is likewise inconsistent with its policy and the Food, Drug, and Cosmetic Act as it has been construed. Instead, the invocation of the adverse effect of Plan B on 11-year-olds is an excuse to deprive the overwhelming majority of women of their right to obtain contraceptives without unjustified and burdensome restrictions.

Some of those burdens are detailed in a research letter published in the Journal of the American Medical Association in January 2012, which described the results of a study that investigated the ability of 17-year-old women to access emergency contraception. Tracey A. Wilkinson et al., *Research Letter: Access to Emergency Contraception for Adolescents*, 307 J. Am. Med. Ass'n 362 (January 25, 2012). In Dr. Wilkinson's study, "female research assistants posing as [17-year-old] adolescents who recently had unprotected intercourse were randomly assigned to call every commercial pharmacy" in five geographically diverse cities and ask about emergency contraception. *Id.* "The study revealed that approximately 20% of pharmacies did not have emergency contraception available on the same day that the patient called the pharmacy." Wilkinson Decl. ¶ 7, Case No. 12-cv-763, Doc. No. 6. In addition, "in 19% of the calls, the caller was incorrectly told she could not access emergency contraception at all because of her age, despite the fact that the FDA regime allows over-the-counter access by 17-year-olds." *Id.* ¶ 8. Dr. Wilkinson expressed her shock that "close to 1 in 5 calls made by adolescents resulted in them being told they could not access emergency contraception at all." *Id.* "[T]he rate of misinformation," Dr. Wilkinson explained, "was statistically significantly worse in low-income neighborhoods." *Id.* In addition, Dr. Wilkinson's study showed that "of the 943 pharmacies called, only 4.7% of them were open 24 hours." *Id.* ¶ 9.

All of these barriers, not to speak of the need for adolescents under 17 to find a doctor and obtain a prescription, "are created or exacerbated by the FDA's unusual treatment of emergency contraception [and] can have the cumulative effect of preventing some women from accessing the drug within the short time frame during which it will be effective, thereby exposing them to increased risk of unwanted pregnancy and making the product's limited OTC status useless. Unfortunately, this risk is especially great for young women and low-income women, two groups that could significantly benefit from timely access to and use of the product." *Id.* ¶ 10.

I pause to add these brief words before I begin the discussion of the legal issues. This case has proven to be particularly controversial because it involves access to emergency contraception for adolescents who should not be engaging in conduct that necessitates the use of such drugs and because of the scientifically unsupported speculation that the drug could interfere with implantation of fertilized eggs. Nevertheless, the issue in this case involves the interpretation of a general statutory and regulatory scheme relating to the approval of drugs for over-the-counter sale. The standards are the same for aspirin and for contraceptives. While the FDA properly recognizes that cognitive and behavioral differences undermine "the ability of adolescents to make reasoned decisions about engaging in sexual intercourse," the standard for determining whether contraceptives or any other drug should be available over-the-counter turns solely on the ability of the consumer to understand how to use the particular drug "safely and effectively." Ex. A-4 to Pls.' 2007 Mot. for Summ. J. at T-31097, Case No. 05-cv-366, Doc. No. 235-5. I decide this case based only on my understanding of the applicable standard.

II. DISCUSSION

A. Procedural Posture

Secretary Sebelius's directive to the FDA to reject the Plan B One-Step SNDA forced the agency to ride roughshod over the policies and practices that it has consistently applied in considering applications for switches in drug status to over-the-counter availability. Before reviewing these unexplained and unjustified departures, a brief discussion of the procedural posture of the case is necessary, although I pass over much of its complicated history. The directive of the Secretary did not directly apply to the Citizen Petition, the denial of which I have subject matter jurisdiction to review. Nevertheless, the denial of the Citizen Petition was inevitable after the Secretary ordered the FDA to reject the SNDA for Plan B One-Step because the Secretary concluded that the sponsor's "label comprehension and actual use studies . . . do not include data on all ages for which the drug would be approved and available over-the-counter." Sebelius Mem. This pronouncement made it impossible as a practical matter for the FDA to approve the Citizen Petition, because it likewise did not include such data. Indeed, the Citizen Petition denial came only five days later, although the FDA had sat on the Citizen Petition for three years.

The plaintiffs have moved for a preliminary injunction and summary judgment. In essence, they ask that the Citizen Petition be granted and that FDA be required to make all levonorgestrel-based emergency contraception, including Plan B, available for over-the-counter sales without age or point of sale restrictions. The defendants have cross-moved for summary judgment. While they incorporate, in one sentence, arguments that they made earlier in this proceeding, their motion centers on the argument that the FDA has no set policy of extrapolating data from adults to pediatric populations.

B. Deviations from Policy

In *INS v. Yang*, 519 U.S. 26 (1996), the Supreme Court held: "Though the agency's decision is unfettered at the outset, if it announces and follows—by rule or by settled course of adjudication—a general policy by which its exercise of discretion will be governed, an irrational departure from that policy (as opposed to an avowed alteration of it) could constitute action that must be overturned as 'arbitrary, capricious, [or] an abuse of discretion' within the meaning of the Administrative Procedure Act." *Id.* at 32; *see also Office of Commc'n of the Church of Christ v. FCC*, 560 F.2d 529, 532 (2d Cir. 1977) ("Here the Commission is seeking to change its policy, and . . . such changes in policy must be rationally and explicitly justified in order to assure that the standard is being changed and not ignored, and . . . that (the agency) is faithful and not indifferent to the rule of law. Although an agency must be given flexibility to reexamine and reinterpret its previous holdings, it must clearly indicate and explain its action so as to enable completion of the task of judicial review.") (internal quotation omitted). The denial of the SNDA and the Citizen Petition was accomplished by unexplained departures from a number of established policies and practices followed by the FDA.

1. The Unprecedented Intervention of the Secretary

Perhaps the most significant departure from agency practice was the intervention of the Secretary of Health and Human Services. She overruled the FDA in an area which Congress entrusted primarily to the FDA, 21 U.S.C. § 393(d)(2), and which fell within the scope of the authority that the Secretary expressly delegated to the Commissioner. *See* Delegations of Authority to the Commissioner of Food and Drugs, *republished in* FDA Staff Manual Guide § 1410.10. In doing so, she failed to take cognizance of a host of FDA policies that the agency would be forced to override in order to comply with her directive.

In my 2009 opinion, I traced the evidence demonstrating that the conduct of the FDA was influenced by the Bush White House, acting through the Office of the Commissioner of the FDA, and I held that this kind of political interference called into serious question the legitimacy of the FDA's decision. In the present circumstances, the political interference came directly from the Secretary of Health and Human Services, a member of the President's Cabinet. Of course, the Secretary herself is the best source of information on her state of mind, and she has not seen fit to file an affidavit in this case, even though her motives are in issue. *See, e.g.*, First Am. Supp. Compl. ¶ 38, Case No. 12-cv-763, Doc. No. 14; *cf. Campbell v. United States*, 365 U.S. 85, 96 (1961) ("[T]he ordinary rule, based on considerations of fairness, does not place the burden upon a litigant of establishing facts peculiarly within the knowledge of his adversary.")

Nevertheless, we have been cautioned that, as judges, we "cannot shut our eyes to matters of public notoriety and general cognizance. When we take our seats on the bench we are not struck with blindness, and forbidden to know as judges what we see as men [and women]." *Ho Ah Kow v. Nunan*, 12 F. Cas. 252, 255 (C.C.D. Cal. 1879) (No. 6546); *see also Watts v. Indiana*, 338 U.S. 49, 52 (1949) (Frankfurter, J.) ("[T]here comes a point where this Court should not be ignorant as judges of what we know as men [and women]."). The motivation for the Secretary's action was obviously political. "It was the first time a cabinet member had ever publicly countermanded a determination by the F.D.A., the agency charged with ensuring the safety of foods and medicines." Gardiner Harris, *White House and the FDA Often at Odds*, N.Y. Times, Apr. 3, 2012 at A1. And it was an election-year decision that "many public health experts saw as a politically motivated effort to avoid riling religious groups and others opposed to making birth control available to girls." *Id.* Thus, three distinguished scientists, including the Editor-in-Chief of the New England Journal of Medicine, wrote:

> In our opinion, the secretary's decision to retain behind-the-counter status for Plan B One-Step was based on politics rather than science. It cannot be based on issues of safety, since a 12-year-old can purchase a lethal dose of acetaminophen in any pharmacy for about $11, no questions asked. The only documented adverse effects of a $50 dose of levonorgestrel are nausea and delay of menses by several days. Any objective review makes it clear that Plan B is more dangerous to politicians than to adolescent girls.

The Politics of Emergency Contraception, 366 New Eng. J. Med. 101, 102 (Jan 12, 2012).

Nevertheless, even with eyes shut to the motivation for the Secretary's decision, the reasons she provided are so unpersuasive as to call into question her good faith. While the Secretary has strung together three factual statements in her memorandum to Commissioner Hamburg, she has failed to offer a coherent justification for denying the over-the-counter sale of levonorgestrel-based emergency contraceptives to the overwhelming majority of women of all ages who may have need for those drugs and who are capable of understanding their correct use. I proceed to deconstruct her explanation sentence by sentence.

a. The First Sentence

The Secretary says that "[t]he label comprehension and actual use studies submitted to FDA do not include data on all ages for which the drug would be approved and available over-the-counter." Sebelius Mem. This statement ignores the fact that the FDA waived the requirement that included a minimum number of enrollees between the ages of 11 and 13 in the drug sponsor's studies. Defs.' Resp. to Mar. 4, 2013 Order at 2, Case No. 12-cv-763, Doc. No. 79; *see also* Tina R. Raine et al., *An Over-the-Counter Simulation Study of a Single-Tablet Emergency Contraceptive in Young Females*, 119 Obstetrics & Gynecology 772, 775 (2012), Case No. 12-cv-762, Doc. No. 26-1. In effect, the Secretary ordered the FDA to deny the application of the Plan B One-Step sponsor because it lacked data that the FDA itself had told the sponsor it did not have to provide. This the Secretary does not deny. The excuse offered by

the minyan of attorneys representing her is that the Secretary was "not present" at the meeting where the FDA agreed to waive this data and that she disagreed. Defs.' Resp. to March 4, 2013 Order at 2, Case No. 12-cv-763, Doc. No. 79. They are careful to avoid saying she did not have knowledge of the waiver. Moreover, as discussed below, the Secretary may not issue administrative edicts simply because she disagrees with the decisions of the FDA.

b. The Second Sentence

The Secretary also observed that there are "significant cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age," which she believes "are relevant to making this determination as to non-prescription availability of this product for all ages." Sebelius Mem. She fails to explain why. The issue of the cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age to which the Secretary alluded was raised in the FDA's review of the first SNDA for Plan B. In response, Dr. John Jenkins, Director of the Office of New Drugs at the FDA, explained that such concerns are beyond the scope of the FDA's review because they are "more applicable to the ability of adolescents to make reasoned decisions about engaging in sexual intercourse, not their ability to understand how to use Plan B safely and effectively as an emergency contraceptive should they engage in unprotected sexual intercourse." Ex. A-4 to Pls.' 2007 Mot. for Summ. J. at T-31097, Case No. 05-cv-366, Doc. No. 235-5. While recognizing that "OTC access to Plan B for adolescents may be controversial from a societal perspective," Dr. Jenkins could not "think of any age group where the benefit of preventing unplanned pregnancies and abortion is more important and more compelling." *Id.* at T-31098. Indeed, slightly over half of teenage mothers obtain a high school diploma by age 22, compared to 89 percent of women who didn't have a teen birth. The National Campaign to Prevent Teen and Unplanned Pregnancy, *Why it Matters:*

Teen Childbearing, Education, and Economic Wellbeing at 1 (July 2012). "Another study found that less than two percent of young teen mothers attain a college degree by age 30 . . . . Between 2009 and 2010, roughly 48 percent of all mothers age 15 to 19 lived below the poverty line . . . . As their children grow older, their likelihood of living in poverty increases."[4] *Id.* at 1-3.

On the other hand, as seems clear from the Secretary's explanation, if the "cognitive differences" to which she referred affected the ability of the youngest adolescents to understand the label and use the drug appropriately, then it would be impossible for any drug to be approved for over-the-counter sales without a prescription. This would thwart the intent of Congress to "relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician." S. Rep. No. 82-946 (1951), *reprinted in* 1951 U.S.C.C.A.N. 2454, 2454.

Specifically, census statistics demonstrate that there are fewer than two million 11-year-old girls in the United States. U.S. Census Bureau, *Age and Sex Composition in the United States: 2011*, *available at* http://www.census.gov/population/age/data/2011comp.html. As the Secretary noted, "about ten percent of girls reach menarche by 11.1 years of age"; thus, there are fewer than 200,000 11-year-old girls of reproductive age in the country. Moreover, fewer than 3% of girls under the age of 13 are sexually active. Tina R. Raine et al., *An Over-the-Counter Simulation Study of a Single-Tablet Emergency Contraceptive in Young Females*, 119 Obstetrics & Gynecology 772, 779 (2012), Case No. 12-cv-762, Doc. No. 26-1. Thus, the potential population about whom the Secretary is concerned is infinitesimal, even if all of these young adolescents are unable to read a relatively simple emergency contraception label and use the drug

[4] These disturbing statistics underscore the President's own concern with the problems caused by teen pregnancy. As one commentator has observed, the President "has invested many millions of dollars to battle teenage pregnancy and fought to include contraception in his health plan. Contraception, study after study shows, plays a central and inescapable role in pushing down the number of pregnant teenagers." Michael Powell, *Bloomberg's Shame-and-Blame Tactic on Teenage Pregnancy*, N.Y. Times, Mar. 12, 2013, at A17.

appropriately. By contrast, 12% of the total population of the United States over the age of 16 are deemed to have "below basic" document literacy, a term defined by the National Center for Education Statistics as "the knowledge and skills . . . needed to search, comprehend, and use information from noncontinuous texts in various formats, such as . . . prescription labels." National Center for Education Statistics, *Fast Facts: Adult Literacy*, *available at* http://nces.ed.gov/fastfacts/display.asp?id=69. Obviously, if consumers cannot read and understand a drug label, they are likely to use the drug incorrectly without medical supervision, yet the Secretary has never demanded "data . . . [that] conclusively establish" that 100% of the potential users of a drug can understand the label.[5] Nor has she or the FDA precluded the over-the-counter sale of drugs for that reason.

c. The Third Sentence

The Secretary finally observed that, if the SNDA were granted, Plan B One-Step would be available "without a prescription or other point-of-sale restrictions, even to the youngest girls of reproductive age," including the ten percent of girls who "reach menarche by 11.1 years of age." Sebelius Mem. Nevertheless, the Secretary does not define any harm that could result from the use of levonorgestrel-based emergency contraceptives by this population. Again, levonorgestrel-based contraceptives would be probably among the safest drugs approved for over-the-counter sale for the pediatric population. Indeed, the FDA approves drugs for over-the-counter sale which have either not been shown to be safe for use by the pediatric population or have been shown to be unsafe for such use. The policy of the FDA is to rely on labeling. As Dr. Jenkins testified, age-based labeling restrictions have "been [the FDA's] long-standing way of [] instructing consumers whether they should or should not use a product in a young age group, and

[5] This quote is not from Secretary Sebelius's memorandum to Commissioner Hamburg, but her news release of the same date. *A Statement by U.S. Department of Health and Human Services Secretary Kathleen Sebelius* (Dec. 7, 2011), Case No. 05-cv-366, Doc. No. 339-1.

[the Plan B marketing regime is] a substantial deviation from that practice." Jenkins Dep. at 113:7-16, Case No. 05-cv-366, Doc. No. 235-9. Indeed, as Dr. Andrea Leonard-Segal, Director of the FDA's Division of Nonprescription Clinical Evaluation, wrote, "[r]eliance upon the product label to result in appropriate use is consistent with the tenet that the Agency has applied in the past and continues to apply when determining whether or not a product can be over-the-counter. It is an approach consistent with the regulations." Summary Review for Regulatory Action at 28 (Nov. 30, 2011), Case No. 12-cv-763, Doc. No. 83-1 (hereinafter "Summary Review").

Thus, a diet drug, Alli, "was approved [for over-the-counter sales] for weight loss in 2007 only for adults 18 and older," although it could be purchased by teenagers—a group that may still be "in an active growth phase with continued bone and other organ, maturation and where nutritional requirements are different from those of adults." Defs.' Mem. in Support of Mot. for Summ. J. at 5, Case No. 12-cv-763, Doc. No. 71 (quoting NDA 21-887, Office Director's Decisional Memorandum at 3-4 (Feb. 6, 2007)). The FDA observed that "the balance between active weight loss, while still continuing to have adequate nutritional requirements, would best be achieved [] with active health care provider interaction." *Id.* Consequently, the FDA decided to make the drug available for over-the-counter sales with a warning that it was not intended for use by the pediatric population. The Secretary's edict to the FDA simply reflects the fact of her lack of familiarity with, or her willingness to ignore, the policy of the FDA in dealing with these concerns.

Moreover, the likelihood of unsafe use or misuse with respect to levonorgestrel-based emergency contraceptives is extremely low, and much lower than the dangers of misuse of common over-the-counter medications that are known to be abused by minors and adults, even

though these drugs cause hundreds of deaths every year in the United States. In an internal FDA memorandum regarding the first Plan B SNDA in 2004, Dr. Curtis Rosebraugh, FDA Deputy Director of the Division of OTC Drugs, explained the significant inconsistency between the agency's proposed treatment of Plan B and its treatment of other over-the-counter drugs: "A decision by the Agency to withhold OTC marketing of Plan B for reasons of theoretical abuse by a very small segment of the population despite the great benefit that could be derived from easier access could have ramifications for how we regulate other OTC drugs . . . a natural progression of this line of regulatory reasoning *would require that the Agency remove OTC marketing status for many drugs with known abuses* including dextromethorphan because of reports of adolescent abuse, laxatives because of abuse by people suffering from bulimia, analgesics because of abuse with subsequent health ramifications, or acetaminophen because of its use in suicides." Ex. A to Pls.' 2007 Mot. for Summ. J. at T-30757-58, Case No. 05-cv-366, Doc No. 235-3 (emphasis added). Dextromethorphan, to which Dr. Rosebraugh referred, is a cough suppressant contained in cold medicines that are widely abused by teenagers and sold over-the-counter. An overdose of dextromethorphan can cause "inebriation . . . [a]n altered state of consciousness [and] [m]ind and body dissociation or an 'out-of-body' experience," as well as "blurred vision, body itching, rash, sweating, fever, hypertension, shallow respiration, diarrhea, toxic psychosis, [and] coma." National Drug Intelligence Center, *Intelligence Bulletin: DXM (Dextromethorphan)*, October 2004, *available at* http://www.justice.gov/archive/ndic/pubs11/11563/index.htm. Dextromethorphan abusers "can obtain the drug at almost any pharmacy or supermarket" for only a few dollars. *Id.*

2. The Failure to Make Plan B Available to Older Adolescents

The Secretary did not question the adequacy of the evidence regarding the ability of older adolescents, between the ages of 13 and 16, to understand Plan B One-Step's label and use the drug correctly. Indeed, despite the ample evidence that this age group was able to do so, the Secretary never explained why Plan B One-Step should not be made available to them, nor was the Assistant U.S. Attorney representing the FDA willing to answer the specific question that I posed to him at an early stage in this proceeding of "whether the actual use and labeling comprehension studies conducted by Teva with respect to Plan B One-Step are inadequate with respect to all women under the age of 17 or whether they are inadequate only with respect to those under the age of twelve." Dec. 13, 2011 Order, Case No. 05-cv-366. "[T]he Commissioner of the FDA isn't in a position to be able to answer the question," he said, because the decision to deny the SNDA was made by Secretary Sebelius, not the Commissioner. Dec. 13, 2011 Hr'g Tr. at 5:1-8, Case No. 05-cv-366, Doc. No. 342. The Secretary's lawyers have now come up with the excuse that the Plan B One-Step SNDA "did not seek OTC availability for a specific subset of younger women." Defs.' Resp. to Mar. 4, 2013 Order at 3, Case No. 12-cv-763, Doc. No. 79. Instead, it sought to eliminate all point-of-sale and age restrictions.

The Food, Drug, and Cosmetic Act ("FDCA") does not preclude the Secretary or the Commissioner from granting relief less extensive than that sought by an applicant. Nor does it preclude the Commissioner of the FDA, who clearly had the authority, from doing so. Indeed, 21 C.F.R. § 310.200(b) expressly provides that the Commissioner may initiate, *sua sponte*, a proposal to exempt a drug from prescription-dispensing requirements "when the Commissioner finds such requirements are not necessary for the protection of the public health." Thus, when it became clear in the earlier Plan B process that the FDA would not allow over-the-counter sales

without age restriction, the FDA invited the Plan B sponsor to submit a revised SNDA seeking over-the-counter access only for women over 18. Ex. 2 to Defs.' 2007 Mot. to Dismiss at T-11094-95, Case No. 05-cv-366, Doc. No. 248-4. Moreover, in response to my 2009 order in which the FDA acquiesced, it similarly invited the Plan B sponsor to submit a new application revising the age limit downwards to 17, although such relief had not been requested in the Citizen Petition or by the Plan B sponsor. Thus, it is clear that the FDA's options in responding to over-the-counter switch applications are not as limited as they represent.

The Secretary's failure to limit the scope of her decision to girls under the age of 13 suffers from the same defect as the FDA's original order approving over-the-counter access to Plan B for women over the age of 18, notwithstanding the fact that the same evidence that supported over-the-counter access for 18-year-olds applied equally to 17-year-olds. Nevertheless, I make this point only to highlight the arbitrariness of the Secretary's action and not to suggest that a comparable remedy, which would lower the age of availability to adolescents 14 and over, is a viable or appropriate one. The obstructions in the path of those adolescents in obtaining levonorgestrel-based emergency contraceptives under the current behind-the-counter regime have the practical effect of making the contraceptives unavailable without a doctor's prescription. The basic fact is that most younger adolescents, including "many poor or disadvantaged women," "will be denied access because they do not have a driver's license, passport, or other form of identification with which to verify their age." *The Politics of Emergency Contraception*, 366 New Eng. J. Med. 101-02 (Jan. 12, 2012).

3. Extrapolation

Extrapolation is the use of studies in one age group to support approval of a drug in another age group. The FDA's failure to extrapolate involves the next and perhaps the most

significant unexplained deviation from FDA practice ordered by the Secretary. Adopting the strategy that the best defense is a good offense, the defendants have cross-moved for summary judgment focusing on this issue. The problem is that their offense is not very good. The defendants have not submitted any affidavits or other competent evidence regarding the policy of the FDA in support of their motion for summary judgment. Instead, they rely solely on a 2011 article in which they claim "FDA scientists reviewed the use of extrapolation in 166 drug products submitted for pediatric approval between 1998 and 2008. The authors concluded that FDA did *not* extrapolate efficacy data for 29 products (17.5%), partially extrapolated for 113 products (68%), and fully extrapolated for 24 products (14.5%)." Defs.' Mot. for Summ. J. at 3, Case No.12-cv-763, Doc. No. 71; Julia Dunne et al., *Extrapolation of Adult Data and Other Data in Pediatric Drug-Development Programs*, 128 Pediatrics e1242, e1245 tbl. 1 (Nov. 1, 2011).

The foregoing study addressed only the issue of extrapolation as it related to the efficacy of a particular drug. "Efficacy" within the meaning of the FDCA is established when an applicant proves that a particular drug "will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested." 21 U.S.C. § 355(d). There is no dispute in this case related to the efficacy or safety of levonorgestrel-based emergency contraceptives. *See* Apr. 27, 2012 Hr'g Tr. at 84:24-85:2, Case No. 12-cv-763, Doc. No. 84. Indeed, the FDA observed in its Citizen Petition Denial Letter that Plan B "is already approved as a prescription product, and thus the safety and efficacy in the pediatric population have been established." Letter from Janet Woodcock, Center for Drug Evaluation and Research, FDA, to Bonnie Scott Jones, Center for Reproductive Rights at 9 (Dec. 12, 2011), Case No. 05-cv-366, Doc. No. 341-1 (hereinafter "Citizen Petition Denial Letter"). Moreover, as the authors of the

extrapolation study explained, "[e]xtrapolation of efficacy from adult data occurred in 82.5% of the drug products," and it concluded that "[e]xtrapolating efficacy from adult data or other data to the pediatric population can streamline pediatric drug development and help to increase the number of approvals for pediatric use." Dunne et al. at e1242.

The most striking feature of the defendants' motion for summary judgment is its failure to discuss any of the evidence of extrapolation contained in the record. This evidence is discussed at length in my 2009 opinion, and I briefly summarize it here. As early as April 2002, the FDA informed the Plan B sponsor that results from trials in the adult population could be extrapolated to the postmenarcheal pediatric population. Ex. F–1 to Pls.' 2007 Mot. for Summ. J. at T–30100, Case No. 05-cv-366, Doc. No. 239. Indeed, the FDA assured the Plan B manufacturer that the actual use study it was planning to submit with its anticipated SNDA "appear[ed] to be adequate for filing," even though the study would not include data on all ages to which the drug would be made available over-the-counter. Ex. 3 to Defs.' 2007 Mot. to Dismiss at T-30254, Case No. 05-cv-366, Doc. No. 248-5. In addition, FDA review staff observed that "the body of evidence available" to the FDA in its consideration of adolescent use of emergency contraception was "tremendously augmented" by other behavioral studies involving adult use of emergency contraception; these studies were considered by FDA reviewers in their internal conclusions that Plan B should be available over-the-counter. Ex. A–3 to Pls.' 2007 Mot. for Summ. J. at T-30868, Case No. 05-cv-366, Doc. No. 235-4.

On December 16, 2003, the Advisory Committee of outside experts, empaneled by the FDA Center for Drug Evaluation and Research to provide a recommendation on the Plan B SNDA, voted 23 to 4 in favor of the recommendation to approve Plan B for over-the-counter status without age or point-of-sale restrictions; it voted unanimously that Plan B is safe for use in

a non-prescription setting, and *voted 27 to 1 that the actual use study data submitted by the Plan B sponsor could be generalized to the overall population of potential non-prescription users of Plan B, i.e., data from older age groups could be extrapolated to younger ones.* Ex. 2 to Defs.' 2007 Mot. to Dismiss at T-10749, T–10754, Case No. 05-cv-366, Doc. No. 248-3.[6]

Moreover, responding directly to concerns that the label comprehension and actual use studies enrolled too few young adolescents, the Director of the Office of New Drugs, Dr. John K. Jenkins, noted:

> While it is true that the number of adolescents enrolled in the sponsor's studies was relatively small, these studies did not exclude adolescent women from enrollment and were *conducted in settings that would be expected to capture a representative population of women who currently seek emergency contraception. Therefore, it is likely that the percentage of patients enrolled in these studies is an accurate reflection of the potential users of Plan B in an OTC setting*.

Ex. A–3 to Pls.' 2007 Mot. for Summ. J. at T–30897–98, Case No. 05-cv-366, Doc. No. 235-4 (emphasis added); *see also* Ex. A–1 at T–10949 (Acting Director of the Division of Pediatric Drug Development concurring that number of adolescents enrolled in study reflected their actual use of Plan B and waiving pediatric study because of the minimal number of individuals of that age using Plan B). Indeed, Dr. Jenkins wrote, "the Agency has a long history of extrapolating findings from clinical trials in older patients to adolescents in both prescription and non-prescription approvals, and this practice was recently incorporated into the Pediatric Research and Equity Act (PREA)." Ex. A–3 to Pls.' 2007 Mot. for Summ. J. at T–30898; *see also* 21 U.S.C. § 355c(a)(2)(B)(ii) ("A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group.").

[6] The politically motivated rejection of this recommendation was the first time in ten years that the FDA had failed to follow an advisory committee recommendation regarding over-the-counter switch applications. *See* GAO Report at 29. This time around, the FDA found it unnecessary to convene an advisory committee because "Plan B and Plan B One-Step are exceedingly similar drug products and no controversial data emerged" from the Plan B One-Step SNDA "to generate the need for another advisory committee meeting." Summary Review at 26.

There was other evidence in the record that the FDA routinely extrapolated such data when considering new drug applications or switch applications seeking over-the-counter status for contraceptives. The draft minutes from an internal FDA meeting held in May 2004 contain the following comment regarding the decision not to extrapolate for Plan B: The failure of the FDA "to extrapolate adolescent safety and effectiveness for <14 year old females is not consistent with how CDER handles approval and distribution of prescription oral contraceptives, OTC male contraceptives such as condoms and spermacides or OTC female contraceptives such as gels and sponges." T–1213. This was contained in an initial draft of the minutes, although it was subsequently deleted for reasons which are unclear. Nevertheless, it was an accurate reflection of FDA policy. Indeed, the Government Accountability Office ("GAO"), which conducted an investigation into the FDA's Plan B decision at the behest of several members of Congress, stated that the FDA personnel that it interviewed "noted that the agency has not considered behavioral implications due to differences in cognitive development in prior OTC switch decisions and that the agency has considered it scientifically appropriate to extrapolate data from older to younger adolescents." GAO Report at 5.

More significantly, the FDA did engage in extrapolation in considering the Plan B One-Step SNDA; otherwise, it would not have announced its intention to approve that SNDA and expand access to Plan B One-Step to all women of childbearing age. As Dr. Cynthia Harper, who was one of the investigators on the Plan B One-Step actual use study, submitted by the Plan B One-Step sponsor in support of its SNDA, and the leading author on the related publication, explained:

> An actual use study considers the way that *the target population* of a particular product will use that product. Since only rare 11 year olds might need to use emergency contraception, we would be hard-pressed to find them and include them in the actual use study.

> Moreover, even if it were possible, using herculean and unprecedented efforts to find the very rare 11 year olds seeking emergency contraception and include them in the study, the information gathered would not be particularly useful. No conclusions about 11 year olds as a group could be drawn given the incredibly small number of 11 year olds who are users of emergency contraception.

Harper Decl. ¶¶ 13-14, Case No. 12-cv-763, Doc. No. 3. The FDA agreed.

In an April 2012 article on the Plan B One-Step actual use study, Dr. Harper and others explained that: "Considering that approximately 3% of teens initiate sexual activity before age 13 years, and that only a fraction (fewer than 3%) of visits for any reason to the study clinics during the study period were by teens 13 years and younger, the ages of those who ultimately participated in this study represent the population at risk who might need emergency contraception." Tina R. Raine et al., *An Over-the-Counter Simulation Study of a Single-Tablet Emergency Contraceptive in Young Females*, 119 Obstetrics & Gynecology 772, 779 (2012), Case No. 12-cv-762, Doc. No. 26-1. As Dr. Lisa Mathis, Associate Director of the Office of New Drugs at the FDA, commented in her review of the data submitted in support of the Plan B One-Step SNDA, the low number of adolescents between the ages of 11 to 13 is consistent with the known use of these products in that age group. Summary Review at 15. Specifically, she observed that "[t]he condition and the response to therapy in patients in this age group is expected to be sufficiently similar to patients in the 14-year-old age group and thus data from that age group can be used to support the ability of younger patients to use the medication appropriately." *Id.* Thus, the FDA advised the Plan B One-Step sponsor that "it appears that you have provided adequate information to justify removing the quota for enrollment of 11 to 13-

year-olds as currently specified in your actual use study protocol."[7] Defs.' Resp. to Mar. 4, 2013 Order at 2, Case No. 12-cv-763, Doc. No. 79 (quoting Admin. R. 595).

A similar conclusion to that of Dr. Harper was reached in the label comprehension study conducted by Dr. Elizabeth Raymond. While that study included 54 to 59 subjects between the ages of 12 and 17, Dr. Raymond observed that "[p]eople aged 11 and younger are not the target population for this drug, and indeed I believe that the number of users who are that young is miniscule." Raymond Decl. ¶ 37, Case No. 12-cv-763, Doc. No. 5. This is borne out by the actual use "study experience over the course of a 2-year period and information from published literature showing that very low numbers of females aged 11-13 years present to reproductive health clinics requesting emergency contraception." Tina R. Raine et al., *An Over-the-Counter Simulation Study of a Single-Tablet Emergency Contraceptive in Young Females*, 119 Obstetrics & Gynecology 772, 775 (2012), Case No. 12-cv-762, Doc. No. 26-1.

Moreover, the label comprehension study, half of whose participants were between the ages of 12 and 14, demonstrated "that female adolescents 17 years old and younger can obtain sufficient information from the prototype label to enable safe and effective use of emergency contraception over the counter." Raymond Decl. ¶ 35. So too did a label comprehension study in the same adolescent age group focusing on a two-pill emergency contraception product. M. Cremer et al., *Adolescent Comprehension of Emergency Contraception in New York City*, 113 Obstetrics and Gynecology 840 (2009).

In sum, the defendants' motion for summary judgment does not provide any evidence to contradict a record which shows that the FDA has engaged in extrapolation at the very least from

[7] The FDA's waiver of study data for this age group is also consistent with the authority delegated to the Commissioner to waive pediatric studies if "the necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed)." 21 U.S.C. § 355c(a)(4)(A)(i) & 355c(a)(4)(B)(i); Delegations of Authority to the Commissioner of Food and Drugs, *republished in* FDA Staff Manual Guide § 1410.10.

older to younger adolescents with respect to the issues of actual use and label comprehension. Under these circumstances, the defendants' motion for summary judgment with respect to the issue of extrapolation is denied.

4. Deviations Where Extrapolation Is Not Possible Because Safety Not Established

In the course of their motion for summary judgment, the defendants themselves identified a significant related departure from agency practice. Specifically, when the FDA has declined to extrapolate because of safety concerns, it used labeling to indicate that the drug was not to be made available to children. Again, as Dr. Jenkins testified, age-based labeling restrictions have "been [the FDA's] long-standing way of handling instructing consumers whether they should or should not use a product in a young age group, and [the Plan B marketing regime is] a substantial deviation from that practice." Jenkins Dep. at 113:7-16, Case No. 05-cv-366, Doc. No. 235-9; *see also* Julia Dunne et al., *Extrapolation of Adult Data and Other Data in Pediatric Drug-Development Programs*, 128 Pediatrics e1242, e1246 (Nov. 1, 2011) (observing that, when safety in the pediatric population could not be established, "the pediatric safety data were included in the product label"). Indeed, in the Summary Review for Regulatory Action, Dr. Leonard-Segal wrote that "[r]eliance upon the product label to result in appropriate use is consistent with the tenet that the Agency has applied in the past and continues to apply when determining whether or not a product can be over-the-counter. It is an approach consistent with the regulations." Summary Review at 28.

Consistent with this "tenet," the *defendants* expressly cite two examples in which the FDA allowed drugs to be sold over-the-counter that it *did not consider safe* for use in the pediatric population. Defs.' Mem. in Support of Mot. for Summ. J. at 4-5, Case No. 12-cv-763, Doc. No. 71. Thus, they observe:

> Prilosec OTC was approved for frequent heartburn in 2003 for adults 18 and older. It was not approved for use by those under 18," and they include the following explanation from their internal records: "There are 2% of total prescriptions in the 11 to 20y old age group and children have—in general—not been included in clinical trials; [Prilosec] is not approved for prescription use in adolescents (patients under 18y of age). There were only 100 OTC study subjects under age 18 (17% of whom exceeded the 10-day limit) and a total of 39 cases in SafeTNet. From this information, the Medical Officer concluded that *safety in adolescents has not been established* because: a) age-related responses have not been studied; and b) age-related toxicities cannot be ruled out.

Id. at 5 (emphasis added). Nevertheless, the FDA permitted Prilosec OTC to be sold over-the-counter and without point of sale restrictions with simply a warning on the label that it was not approved for use by children or adolescents.

Similarly, as earlier observed, "Alli was approved [for over-the-counter sales] for weight loss in 2007 only for adults 18 and older." *Id.* The defendants quote the following relevant language from the FDA review:

> Treatment of obesity with the intent of weight loss in 12 to 17 year olds is complicated by the factor that this age group includes individuals that may still be in an active growth phase with continued bone and other organ, maturation and where nutritional requirements are different from those of adults. Therefore, the balance between active weight loss, while still continuing to have adequate nutritional requirements, would best be achieved in my judgment with active health care provider interaction. *As such, I do not feel that this age group should be included in an over-the-counter label.*

Id. (emphasis added).

While some over-the-counter drugs, such as Prilosec OTC, probably would not be purchased by adolescent consumers without the advice of a doctor, the same cannot be said for drugs such as Alli, a weight-loss drug that is likely to attract teenage purchasers concerned about their physical appearance rather than medical necessity. Nor can it be said of cough syrup containing dextromethorphan, which is regularly abused by teenagers. The FDA's willingness to rely on labeling to make these drugs available for sale over-the-counter without any age or point-

of-sale restrictions, even though they are unsafe for unsupervised use by young adolescents, stands in stark contrast to its refusal to make equally available concededly safe and time-sensitive levonorgestrel-based emergency contraceptives.

5. Point-of-Sale Departure from Policy

While I have focused on the numerous policy departures as they relate to the age-based restriction to the over-the-counter sale of levonorgestrel-based emergency contraception, an equally significant part of the current regime is its restriction on where these products can be purchased. The validity of this restriction was not addressed in my 2009 opinion. The regime, which the Secretary forced the FDA to retain, requires that the product be sold only at pharmacies and health clinics and that it be kept behind the counter at pharmacies. This point-of-sale restriction not only limits young adolescents' access to Plan B, it limits the access of individuals 17 and older to the product.

In their memorandum of law in support of their motion for summary judgment that preceded my 2009 opinion, plaintiffs invoked *Am. Pharm. Ass'n. v. Weinberger*, 377 F. Supp. 824 (D.D.C. 1974), *aff'd on the opinion below sub nom. Am. Pharm. Ass'n v. Mathews*, 530 F.2d 1054 (D.C. Cir. 1976) (per curiam), for the proposition that the FDCA does not authorize the FDA to limit the sale of approved drugs to particular businesses, such as certain pharmacies and health care clinics. Pls.' Mem. in Supp. of 2007 Mot. for Summ. J. at 110-11, Case 05-cv-663, Doc. No. 236.

Pursuant to 21 U.S.C. § 355(d), the FDA may refuse new drug application approval where the data submitted does not show that the "drug is *safe* for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." *Am. Pharm. Ass'n*, 377 F. Supp. at 828 (emphasis added). Because the FDA "conclud[ed] that [methadone was]

inappropriate for regular [new drug application] approval," it permitted its dispensation only at "certain specified outlets," such as approved hospital pharmacies. *Id.* at 825, 827. In so doing, it created "a unique classification for methadone" that was more restrictive than the regular prescription drug dispensing regime. *Id.* at 827.

In *American Pharmaceutical Ass'n*, the FDA interpreted "safe" to mean that the drug is "secure from possible misuse," and justified the challenged regulation on the grounds that methadone had a high risk of misuse and abuse. *Id*. at 828. The District Court for the District of Columbia, whose opinion was adopted by the D.C. Circuit, rejected this interpretation and held that "safe" within the meaning of the FDCA "was intended to include *only the inherent safety of the drug when used in the manner intended.*" *Id*. (emphasis added). Consequently, the FDA did not have the authority under the FDCA to further limit sales of methadone to specific pharmacies once it had been found safe for its intended use as a prescription drug.[8]

The FDA argued in the earlier proceedings before the 2009 remand that *American Pharmaceutical Ass'n* was distinguishable because the FDA did not mandate marketing limitations for Plan B; instead, it approved marketing limitations that were proposed by the Plan B sponsor. *See* Defs.' Reply Mem. at 42, Case No. 05-cv-366, Doc. No. 265. The Plan B sponsor was clearly allowed to regulate its own point of sale, the FDA argued, and if the sponsor disagreed with the FDA's advice, it had options, such as pursuing administrative and judicial review of the agency's rejection of its original SNDA. *Id.*

Although it is technically true that the Plan B sponsor submitted a revised SNDA asking for this "intermediate class" of drug distribution, it is clear that the sponsor revised its SNDA

[8] Since *Am. Pharm. Ass'n* was decided, it took an act of Congress (rather than FDA regulation) to impose a controlled marketing regime on cold medicines containing pseudoephedrine. Combat Methamphetamine Epidemic Act of 2005, Pub. L. No. 109-177, Title VII, 120 Stat. 192, 256. The legislation required those medicines to be kept in a secure location and required consumers to present photo identification before purchasing them.

only after the FDA informed it that upper management had raised concerns which made it highly unlikely that the OTC switch would be approved for all ages. Indeed, the revised SNDA, filed in March 2004, noted that:

> Although [the sponsor] believes and maintains that Plan B is safe and effective for true OTC use and should be approved as such, we understand that FDA is concerned about adolescent use. Therefore [we are] willing to consider circumstances in which Plan B would be approved for OTC use by women age sixteen and older, while maintaining prescription status for women under age sixteen.

Letter from Barr Research, Inc. to Daniel Shames, M.D., Center for Drug Evaluation and Research, FDA at 1 (Mar. 11, 2004), Case No. 05-cv-366, Doc. No. 248-8. The sponsor recognized that adoption of "such an age restriction" would require, "as a practical matter, [that] the product [] be sold only in stores that have a licensed pharmacy and thus would be available only when the pharmacy is open . . . [and that] the product must be stored behind the counter." *Id*. at 4.

These restrictions, which were adopted by the Plan B sponsor and which were crucial to the FDA's ultimate approval of nonprescription access for women 18 and older, were not adopted voluntarily by the drug company. Thus, the FDA's attempt to distinguish *American Pharmaceutical Ass'n* on this ground fails. The central holding of *American Pharmaceutical Ass'n* is that the FDA's authority over nonprescription drugs does not extend to restricting the point-of-sale distribution of drugs that have been found to be safe "when used in the manner intended." *Am. Pharm. Ass'n,* 377 F. Supp. at 828. The FDA did not challenge, much less address, this holding. Indeed, rather than rely on § 355(d), it argued that FDA regulations, specifically 21 C.F.R. § 314.520, expressly authorized it to restrict distribution of Plan B to select pharmacies and health clinics. Defs.' Reply Mem. at 42-45, Case 05-cv-366, Doc. No.

265. In support of this authority, the FDA lists several drugs that are available only under restricted marketing regimes for safety reasons. *Id.*

This argument is unconvincing. As an initial matter, the FDA admitted that it did not rely on 21 C.F.R. § 314.520 in approving the Plan B SNDA even though it was promulgated in 1992, more than 10 years before the first Plan B SNDA was submitted. *Id.* at 42. Moreover, 21 C.F.R. § 314.520 applies only to drugs "treating serious or life-threatening illnesses." 21 C.F.R. § 314.500. The FDA amended 21 C.F.R. § 314, in part, to permit approval of such drugs "at the earliest possible point at which safety and efficacy can reasonably be established under existing law." 57 Fed. Reg. 13234, 13234 (Apr. 15, 1992). To obtain accelerated approval the drug manufacturer or sponsor is required to conduct "postmarketing stud[ies] to elaborate on the evidence of effectiveness." *Id.* The FDA also adopted procedures for approving, with restrictions on distribution, certain "highly toxic drugs" which could "not [be] shown to be safe under" 21 U.S.C. § 355 "[w]ithout the restriction specified in the approval." 57 Fed. Reg. at 13237. The FDA "emphasized that these restrictions will be considered necessary only rarely and in extraordinary cases. FDA believes that the safe use of most prescription drugs will continue to be ensured through traditional patient management by health professionals and through necessary safety warnings on the drug's labeling." *Id.*

The FDA did not attempt to reconcile the underlying purpose of § 314—to achieve the expedited or accelerated approval of certain drugs—with the long and tortured approval process of the Plan B dual marketing regime. Nor did it argue that Plan B is "highly toxic" or that it is used to treat "a serious or life-threatening illness." Whether an illness is "serious or life-threatening" "is based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more

serious one." 57 Fed. Reg. at 13235; *see also* 52 Fed. Reg. 19466, 19467 (May 22, 1987) (listing examples of serious or life-threatening diseases).

Plan B does not fit within the class of drugs § 314.520 was designed to restrict. This is made clear by the examples the FDA offered of "several other FDA-approved drugs that are distributed under restricting marketing plans pursuant to 21 C.F.R. § 314.520." Defs.' Reply Mem. at 44, Case No. 05-cv-366, Doc. No. 265. Each of the drugs the FDA mentioned is highly toxic and/or has serious health risks associated with its use: Accutane, which is used to treat severe acne, "may cause birth defects if ingested while pregnant"; Trovan, which treats infections, "can cause serious liver disease"; Xyrem, which treats narcolepsy, "had serious side effects [including some events that resulted in death] and had been [designated a Schedule III Controlled Substance because it was] abused as a recreational drug"; and Mifeprex (known as RU-486 in Europe), which is used to end early pregnancy, causes vaginal bleeding which, in some cases, can only be stopped by surgical procedure. *Id.* at 44-45. There is no serious health risk associated with use of Plan B as prescribed and intended, much less one that would make "restrictions on distribution . . . necessary for [its] safe use." 57 Fed. Reg. 58942, 58942 (Dec. 11, 1992). Indeed, the FDA did not identify any health concerns associated with adult or pediatric use of Plan B, and has admitted that Plan B's "safety and efficacy in the pediatric population have been established." Citizen Petition Denial Letter at 9.

Perhaps more significant is the FDA's consideration of its authority to require post-marketing restrictions on nonprescription drugs which it had found safe. In 1984, more than 20 years before the Plan B sponsor submitted the initial SNDA, the FDA denied a citizen petition urging it to establish a class of non-prescription drugs products to be sold only by a pharmacist. Relying in part on *American Pharmaceutical Ass'n*, the FDA Commissioner at the time wrote:

> [T]he agency believes it is questionable whether the distribution of lawfully marketed OTC drugs can be restricted [to a pharmacist-only class] under current statutory provisions. *Under the [FDCA] there is no provision for an intermediate class of drugs between OTC and prescription products.* The statutory requirement that a drug either be limited to prescription dispensing or available OTC with adequate directions for use seems to preclude the agency from establishing a class of drugs whose labeling would need to be supplemented by a pharmacist's instructions.

Ex. E to Pls.' 2007 Mot. for Summ. J. at E-022, Case No. 05-cv-366, Doc. No. 235-10 (emphasis added).

Consistent with this policy, the FDA has voiced concerns in this proceeding about its authority to impose an age-restricted marketing regime on an approved drug. Thus, in 2005, it decided to ask for public comments on whether it needed to resort to rulemaking to impose such a dual marketing regime. *See Tummino*, 603 F. Supp. 2d at 535. The FDA received approximately 47,000 public comments and hired an outside company to review and summarize them. *Id.* That review was completed six months later, at which point the FDA ultimately concluded that it was not necessary to engage in rulemaking before instituting an age-restricted point-of-sale marketing regime. *Id.* While this was going on, the FDA's attorney stated at a 2006 hearing that the FDCA "does not provide the agency—at least it does not clearly provide the agency with the statutory authority to make that kind of age based distinction." July 26, 2006 Hr'g Tr. at 19:11-14, Case No. 05-cv-366, Doc. No. 185. He further explained that "[t]here is no behind the counter option available under federal law," because "*[u]nder the [FDCA], a product is either Rx only or non-prescription.*" *Id.* at 20:14-20. Nevertheless, consistent with its practice of applying its policies based on political expediency, the FDA announced a few days later that over-the-counter sales could be approved for women 18 and older "in a matter of weeks." Stephanie Saul, *F.D.A. Shifts View on Next-Day Pill*, N.Y. Times, Aug. 1, 2006, at A1. This announcement was made one day before the Senate committee hearing on Dr. Andrew von

Eschenbach's confirmation as Commissioner of the FDA, when it was obvious that he would not otherwise be confirmed. *See Tummino,* 603 F. Supp. 2d at 535-36. No other explanation was offered for the departure from the policy unequivocally articulated by the United States Attorney that "[u]nder the [FDCA], a product is either Rx only or non-prescription."

I agree that the FDA did not have the authority to mandate point-of-sale restrictions on drugs approved for nonprescription sale that it found to be safe and effective for all women of childbearing age. Nevertheless, even if it had such authority, it clearly deviated from the policy here. This is demonstrated not only by the drugs that were either not shown to be safe or were unsafe for the pediatric population such as Prilosec and Alli, which were dealt with through labeling, not point-of-sale restrictions, but also by the recent express acquiescence of the FDA in a college's provision of Plan B One-Step to its students through a vending machine. *FDA OK with college's Plan B contraceptive vending machine*, MSN News, Jan. 29, 2013, *available at* http://news.msn.com/us/fda-ok-with-colleges-plan-b-contraceptive-vending-machine. The only condition on access to the vending machine was that students swipe their college ID; the school had previously verified that all of its students were age 17 or over. *Vending machine dispenses emergency contraception*, CNN News, Feb. 8, 2012, *available at* http://www.cnn.com/2012/02/08/us/plan-b-vending-machine.

C. Standard of Review

I have discussed at some length the Secretary's ukase to the FDA to deny the application to make Plan B One-Step available over-the-counter. The Plan B One-Step sponsor has not taken an appeal to the Court of Appeals for the District of Columbia, which would have jurisdiction to review it. *See* 21 U.S.C. § 355(h). The only decision subject to review here is the denial of the Citizen Petition; I do not have any authority to review the denial of the Plan B One-

Step SNDA for the purpose of granting relief. Nevertheless, as observed earlier, the two were clearly linked together for two reasons. First, once the Secretary directed the FDA to deny the Plan B One-Step SNDA, the FDA had no possible basis on which to approve the Citizen Petition. The same lack of data that the Secretary said caused her to deny the Plan B One-Step SNDA also doomed the Citizen Petition because it lacked the same data, which were, as the FDA acknowledged, impossible to provide. I discuss this issue in full below. Second, it is not possible to exercise meaningful judicial review over the denial of the Citizen Petition without considering the propriety of the Secretary's actions regarding the Plan B One-Step SNDA. Indeed, the FDA's own justification for its Citizen Petition action indicates a substantial reliance on the Plan B One-Step SNDA process. The FDA spent a considerable portion of the Citizen Petition Denial Letter discussing the Plan B One-Step SNDA and the various studies submitted in its support. More significantly, the very reason the FDA claimed it denied the Citizen Petition was the lack of age-specific data, *as compared to* that submitted with the Plan B One-Step SNDA.

The applicable standard of review is prescribed by the Administrative Procedure Act ("APA"), which provides that a district court may set aside an agency's findings, conclusions of law or action only if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An agency decision may be deemed arbitrary and capricious:

> [I]f the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *accord Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 79 (2d Cir. 2006). Moreover, as I have previously observed, if an agency adopts a general policy by which its discretion is exercised, "an irrational departure from that policy (as opposed to an avowed alteration of it) could constitute action that must be overturned as 'arbitrary, capricious, [or] an abuse of discretion' within the meaning of the [APA]." *INS v. Yang*, 519 U.S. 26, 32 (1996). Similarly, "proof of subjective bad faith by [agency decision-makers], depriving a [petitioner] of fair and honest consideration of its proposal, generally constitutes arbitrary and capricious action." *Latecoere Int'l, Inc. v. U.S. Dept. of Navy*, 19 F.3d 1342, 1356 (11th Cir. 1994); *James Madison Ltd. v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996) (Bad faith is "material to determining whether the Government acted arbitrarily."). Moreover, the standard of review is somewhat less deferential when considering an agency order "that arrives at substantially the same conclusion as an order previously remanded by the same court." *Greyhound Corp. v. Interstate Commerce Comm'n*, 668 F.2d 1354, 1358 (D.C. Cir. 1981).

Because the arbitrary and capricious standard of review is deferential, the defendants have sought to recast the Secretary's decision as that of the FDA in order to confer upon the Secretary the deference to which the FDA is due as a result of its specialized experience and judgment. This argument fails for a number of reasons. First, there was only one "ultimate decision-maker on the SNDA," and that was the Secretary. Letter from the United States Attorney at 2 (Mar. 14, 2013), Case No. 12-cv-763, Doc. No. 80. Second, the Secretary was obviously unaware of the policies followed by the FDA in deciding applications to switch a drug's prescription status, or she consciously ignored them. Third, while the rationale for deferring to an agency's decision-making is "particularly strong when the [agency] is evaluating

scientific data within its technical expertise," *Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992), normally the Secretary of Health and Human Services has no specialized technical expertise in this area. Indeed, it is safe to say that most of those who hold that position are not qualified to serve as Commissioner of the FDA.

This explains why Congress expressly delegated to the FDA, among other responsibilities, the decision whether to allow drugs to be sold without a prescription. Indeed, the language of the FDCA specifically provides that "the Secretary, *through the Commissioner*, shall be responsible for executing" the FDCA—language which deprived the Secretary of the authority to deny either the SNDA or the Citizen Petition on her own. 21 U.S.C. § 393(d)(2) (emphasis added). Just as the Secretary could not, on her own, deny either of the two petitions at issue here, she should not be able to overrule the decision of the FDA without good reason.

> The FDA is an expert scientific agency charged with making scientific and medical decisions within the boundaries set by the FDCA. Nothing in that statute suggests that scientific decisions may bend to political winds. There are more than a dozen scientific areas of expertise that are brought into account when making a decision on a NDA or Supplemental NDA—e.g., clinical medicine (here obstetrics and gynecology), pediatrics, toxicology, clinical pharmacology, and statistics, among many others. NDAs and Supplemental NDAs are lengthy, complex, highly sophisticated applications that must comply with a myriad of FDA regulations which in turn are concordant with international standards.

Pendergast Decl. ¶ 33, Case No. 12-cv-763; Doc. No. 4. *See also* Hamburg Statement, Case No. 05-cv-366, Doc. No. 339-2 ("Our decision-making reflects a body of scientific findings, input from external scientific advisory committees, and data contained in the application that included studies designed specifically to address the regulatory standards for nonprescription drugs.").

In apparent recognition of the complexity of this process, the Secretary has delegated to the Commissioner of Food and Drugs, with the authority to re-delegate, "[f]unctions vested in the Secretary under the [FDCA] (21 U.S.C. 301 et seq.)." Delegations of Authority to the

Commissioner of Food and Drugs, *republished in* FDA Staff Manual Guide § 1410.10. This necessarily includes the authority, if any, of the Secretary to make decisions on drug approvals pursuant to 21 U.S.C. § 355.[9] This delegation is consistent with language Congress used in the legislation that made the Commissioner of the FDA a presidential appointee subject to Senate confirmation.

The change in the status of the Commissioner was based on a finding that "the independence and integrity of the Food and Drug Administration need to be enhanced in order to ensure the continuing protection of the public health." Food and Drug Administration Act of 1988, Pub. L. No. 100-607, § 502, 102 Stat. 3048, 3120. One consequence of this change was that the Commissioner was no longer a subordinate of the Secretary. She does not serve at the pleasure of the Secretary, and she cannot be removed from office by the Secretary. Only the President has the power to do so. In this case, if Commissioner Hamburg had refused to follow the directive of Secretary Sebelius, the President would have been faced with the unpalatable choice of either dismissing the Commissioner or overruling the Secretary.

Moreover, even in the run-of-the-mill case under the APA, courts "do not hear cases merely to rubber stamp agency actions. To play that role would be 'tantamount to abdicating the judiciary's responsibility under the Administrative Procedure Act.'" *Nat'l Res. Def. Council v. Daley*, 209 F.3d 747, 755 (D.C. Cir. 2000) (quoting *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995)). Thus, even if the Secretary is entitled to the benefit of the same deference to which the FDA would be entitled, that deference does not entitle her opinion to a judicial rubber-stamp. If anything, the unprecedented nature of her interference with the administration of Chapter 9 of the FDCA, her lack of scientific expertise, and her failure to

[9] The Delegation of Authority includes a reservation of the Secretary's right to approve FDA regulations in some circumstances. *Id.* § 2(A). There is, however, no reservation of any right to intervene in over-the-counter product approvals. See Decl. of Mary Pendergast, J.D., L.L.M., ¶ 34, which I treat as the equivalent of an amicus brief.

acknowledge, much less explain, the deviations from FDA policy occasioned by her order to the FDA suggest that an even more careful examination of her action is warranted. So too does the fact that this case involves the constitutional right to obtain and use contraceptives. The restriction on the sale of time-sensitive levonorgestrel-based contraceptives to pharmacies and health clinics, which affects all women, implicates this right. Indeed, in considering a challenge to a New York statute that prohibited the sale of any form of contraceptive to a minor under the age of 16 and prohibited anyone other than a licensed pharmacist from distributing contraceptives to persons 16 or over, the Supreme Court framed the right in question as the right to make one's own decision in matters of childbearing—including the right of access to contraception—rather than the right of individuals to obtain contraceptives from individuals other than licensed pharmacists. *Carey v. Population Servs. Int'l*, 431 U.S. 678, 685-689 (1977); *see also Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 69 (1983) (striking down restrictions on advertising for contraceptives not only because such advertising implicates public interest in the free flow of commercial information, but also "relates to activity which is protected from unwarranted state interference").

While the FDA complied with Secretary Sebelius's order, it is clear that the decision to deny the SNDA was not that of an agency to which "Congress has entrusted the responsibility of making the necessary scientific assessment . . . [and which] must have the latitude to make that decision properly." Letter from United States Attorney at 2 (Aug. 13, 2010), Case No. 05-cv-366, Doc. No. 307-4. The decision that the agency was forced to make, contrary to its own policies and judgment, is not entitled to any deference. Indeed, it is hardly clear that the Secretary had the power to issue the order, and if she did have that authority, her decision was arbitrary, capricious, and unreasonable.

D. Citizen Petition Denial

The FDA denied the Citizen Petition almost immediately after it rejected the Plan B One-Step SNDA in December 2011. The FDA's decision was compelled by the reason underlying the Secretary's order to reject the Plan B One-Step SNDA. Again, the Secretary concluded that "[t]he label comprehension and actual use studies submitted to FDA [by the Plan B One-Step sponsor] do not include data on all ages for which the drug would be approved and available over-the-counter." Sebelius Mem., Case No. 05-cv-366, Doc. No. 339-1. The Citizen Petition had to be denied because it suffered from exactly the same defect. Thus, there was no way in which the FDA could have approved the Citizen Petition. Indeed, the United States Attorney's most recent letter does not dispute the fact that the Secretary's denial precluded the FDA from granting the Citizen Petition to the extent that it sought a complete over-the-counter switch for all ages. Letter from the United States Attorney at 4 (March 22, 2013), Case No. 12-cv-763, Doc. No. 83. Instead, she suggests that "if the data in the Citizen Petition docket hypothetically supported lowering the age cut-off for non-prescription sales of that drug from the current 17 to some intermediate age, then FDA could theoretically have initiated a notice-and-comment rulemaking proceeding to consider lowering the cut-off age for Plan B . . . notwithstanding the Secretary's determination with respect to the all-or-nothing SNDA for Plan B One-Step." *Id.* This is not the relief that the Citizen Petition requests and, for the reasons already stated, it would be a pointless remedy.

The fact that the Secretary's order mandated the denial of the Citizen Petition as well as the SNDA could have been explained in one page, if not one sentence. Instead, the FDA produced a ten page document composed mainly of filler that was designed to create the illusion

that it was engaging in some independent exercise of agency discretion. The bizarre nature of the Citizen Petition denial letter is highlighted by the following paragraph:

> Actual use and labeling comprehension data would be needed to determine, among other things, whether women under 17 can understand that they would need to take two pills twelve hours apart, and whether they actually would do so correctly. *The data submitted by Teva in its SNDA for Plan B One-Step included a labeling comprehension study and an actual use study that CDER scientists concluded were necessary and addressed the deficiencies in the original data that led to the earlier bifurcated approval status*. This type of data, i.e., actual use and labeling comprehension studies conducted with adequate numbers of younger subjects, has not been presented to the agency with respect to Plan B. Thus, FDA reconfirms its conclusion that neither the information contained in the administrative record for the citizen petition, nor the data and information in the Plan B SNDAs, were adequate to support OTC use in women under age 17.
>
> Therefore, upon reconsideration and following a re-analysis, we conclude that FDA needs additional data to support a switch of Plan B for women younger than 17 years of age.

Citizen Petition Denial Letter at 10 (emphasis added).

In essence, the FDA was telling the plaintiffs that the Plan B One-Step sponsor had submitted adequate labeling and actual use studies sufficient to support an over-the-counter switch with no age or point-of-sale restrictions and that the Citizen Petition could not be approved unless they submitted the same data. Of course, had they been able to provide such data, the FDA would still have been forced to deny their petition on the grounds articulated by the Secretary. Thus, the suggestion that the plaintiffs need to provide "additional data" comparable to that in the Plan B One-Step application "to support a switch of Plan B for women younger than 17 years of age" is simply a complete pretext—another example of the bad faith that has permeated the FDA's consideration of the Citizen Petition from beginning to end.

Moreover, even considered on its own terms, the Citizen Petition Denial Letter is unsound. Perhaps most significantly, it failed to offer any explanation as to why Plan B should be treated differently from other drugs so as to require numerous deviations from agency policies

and practices. The most significant example is its failure to acknowledge the FDA's own policy and precedent in extrapolating data from older adolescents to younger, particularly with respect to contraceptives, much less explain why the FDA failed to adhere to that precedent. The flawed and failed summary judgment motion on this issue, unaccompanied by any affidavit containing such an explanation, is insufficient.

Even if the failure to extrapolate could somehow be justified, the Citizen Petition Denial Letter also failed to acknowledge the FDA's own policy and precedent of approving drugs for over-the-counter sale even where there is real concern about their safety. No explanation is given as to why, if the data regarding the proper use of Plan B by young adolescents were indeed insufficient, that could not be addressed through a labeling restriction rather than age and point-of-sale restrictions. Nor does the FDA justify the creation and maintenance of a new and unprecedented point-of-sale marketing program—the behind-the-counter regime restricting emergency contraceptives to pharmacies and health clinics—for a drug whose safety and efficacy is unquestioned, and which certainly poses a lesser risk to health than many other drugs sold over-the-counter.

While these unexplained departures from precedent alone render the denial arbitrary, capricious, and unreasonable, they are not the only reasons for reversing the denial of the Citizen Petition. The Citizen Petition Denial Letter claimed that no new data had been submitted by the plaintiffs or any other sources "to satisfy the statutory requirements for FDA to remove the Rx requirements for Plan B for women under the age of 17" since the 2009 remand. Citizen Petition Denial Letter at 10. In addition, the FDA wrote that it did "not have any data from other sources that would be sufficient to support such a switch." *Id.* The latter statement was untrue because the agency did have data from at least two sources.

First, the FDA had available the actual use and label comprehension studies submitted by the Plan B sponsor in support of its SNDAs seeking expanded over-the-counter access to Plan B and Plan B One-Step. Specifically, the label comprehension study submitted with the Plan B One-Step SNDA tested participants' understanding of six key concepts, developed with the FDA's input:

> (1) The product is used to prevent pregnancy after unprotected sex;
> (2) It should be taken as soon as possible after sex;
> (3) It does not prevent sexually transmitted disease or HIV/AIDS;
> (4) It should not be used instead of regular contraception;
> (5) It should be taken within 72 hours after sex; and
> (6) It should not be used by women who are already pregnant.

Raymond Decl. ¶ 33, Case No. 12-cv-763, Doc. No. 5. These six key concepts were understood by 83-96% of all subjects. Raymond et al., *Comprehension of a prototype emergency contraception package label by female adolescents*, 79 Contraception 199, 203 (2009), Case No. 12-cv-763, Doc. No. 27-1. As the article publishing the study states:

> Lower literacy was significantly associated with lower likelihood of understanding of each of the six key concepts. . . . Younger subjects were significantly less likely than older subjects to understand four of the key concepts, although the difference in understanding between 12- to 14-year-olds and 15- to 17-year-olds was no more than 10 percentage points for any one concept.

Id. at 203.

While the label comprehension study submitted with the Plan B One-Step SNDA tested instructions for a one-pill product, "[a]ll six key concepts that were tested in [the] second label comprehension study apply equally well to both one-pill and two-pill products." Raymond Decl. ¶ 36. The Plan B One-Step study "did not test the instruction that in two-pill products, the two pills should be taken 12 hours apart." *Id.* Nevertheless, "substantial data indicate that this interval is irrelevant to efficacy, which is the same whether the two pills are taken 0, 12, or 24 hours apart," and is also irrelevant to safety, as "the pills are equally safe no matter what the

interval." *Id.*; *see also* Medical Officer's Safety Rev. of SNDA at T-30799 (March 25, 2004), Case No. 05-cv-366, Doc. No. 235-3. As the published article on the study states, "[t]he prototype label that we tested was similar in format and content to that of the currently marketed Plan B product." Raymond et al. at 199.[10]

Second, the FDA concedes that, in its independent literature review, it considered the label comprehension study conducted by Dr. Miriam Cremer. Defs.' Resp. to Mar. 4, 2013 Order at 1-2, Case No. 12-cv-763, Doc. No. 79; *see also* M. Cremer et al., *Adolescent Comprehension of Emergency Contraception in New York City*, 113 Obstetrics and Gynecology 840 (2009); Cremer Decl., Case No. 12-cv-763, Doc. No. 29. Dr. Cremer and her team tested the comprehension of over 1,000 adolescents between the ages of 12 and 17 who were provided with "a six-page copy of an actual two-pill levonorgestrel-based package insert that individuals receive when purchasing [emergency contraception]." Cremer Decl. ¶ 4. The results of the study indicated that adolescents "understood the concepts necessary for safe and effective use" of emergency contraception "as well as adults do." *Id.* ¶ 5. "Overall, adolescents demonstrated high comprehension of the key points of EC: 1) that it is a method of preventing pregnancy after unprotected sex (92%); 2) that it has to be taken within the first seventy-two hours after unprotected intercourse (83%); 3) that if you are already pregnant EC will not be effective (87%); 4) that EC will not protect against HIV/AIDS (95%); and 5) that EC should not be used as a method of long-term birth control (85%)." *Id.*

Indeed, the FDA itself acknowledged the "overlapping elements of labeling between Plan B One-Step and the other levonorgestrel [emergency contraception] products. Examples of these

[10] The Plan B sponsor had submitted a similar label comprehension study with its initial SNDA. That study included "656 subjects from 12 to 50 years old, of whom 580 were 17 years and older." Summary Review at 12. "The 2001 study was of similar design" to the Plan B One-Step label comprehension study, "and 13 questions in both studies overlapped. The proportions of subjects who answered correctly were similar for 11 of 13 questions." *Id.*

elements include the indication for the product, the appropriate time to take the product (as soon as possible but within 72 hours), and the warnings that the product should not be used as regular birth control and will not protect from sexually transmitted diseases. In addition, safety data generated by these trials for levonorgestrel used as emergency contraception may be applicable to both products. Therefore, some data generated by these studies may be applicable to the other levonorgestrel [emergency contraceptives]." Letter from Andrea Leonard-Segal, M.D., Center for Drug Evaluation and Research, FDA, to Duramed Pharmaceuticals at 2 (Dec. 17, 2010), Case No. 12-cv-763, Doc. No. 23-3.

In its letter explaining its reasons for rejecting the Citizen Petition, the FDA provided additional insight into the process by which it found Plan B One-Step to be appropriate for over-the-counter access by all ages. The letter observed that, because "[t]his product is already approved as a prescription product . . . the safety and efficacy in the pediatric population have been established." Citizen Petition Denial Letter at 9 (quoting a memorandum of Lisa Mathis, Associate Director of the Office of New Drugs at the FDA). Under these circumstances, additional data were needed only to show "that the benefits and risks would be the same if the product was available OTC without a learned intermediary." *Id.* The FDA official quoted in the letter goes to conclude that "[t]he studies provide data to demonstrate that women of child bearing potential of all ages can appropriately self-diagnose and administer Plan B One-Step in an OTC setting . . . The safety and efficacy of OTC Plan B One-Step in this application is supported by the totality of the data submitted to support the application." *Id.*

Nevertheless, the FDA insisted that the Plan B One-Step actual use study could not be used to support over-the-counter access to Plan B because Plan B involves two pills taken 12 hours apart instead of one pill. Specifically, the FDA said:

> [T]he two drugs are not the same product, and all of the data supporting one application cannot automatically be used for the other. In particular, because Plan B One-Step consists of a single tablet, the dosing data for Plan B One-Step could not provide support for an OTC switch of Plan B as that data would not adequately address the ability of subjects to correctly follow the directions related to the timing of a second dose that is required for proper use of Plan B.
>
> Thus, as a scientific matter, if additional data regarding the OTC use by younger women were needed for Plan B One-Step, that type of data would also be needed for Plan B, but those Plan B One-Step studies would not be transferable to Plan B. Instead, there would need to be new studies conducted using Plan B and its labeling, because it has more complicated directions for use, raising additional questions as to label comprehension and actual use.

Id. at 2.

The approval of Plan B One-Step by the FDA demonstrates its recognition that there would be no adverse consequences or decrease in effectiveness if the two pills were taken at the same time or less than 12 hours apart. The only consequence that the defendants were able to identify from a failure to follow the label instructions is that "if you miss the timing of the second dose, it reduces effectiveness and that can have unfortunate consequences for someone who is taking the drug to avoid becoming pregnant." Apr. 27, 2012 Hr'g Tr. at 84:9-12, Case No. 12-cv-763, Doc. No. 84. This is the argument of a lawyer, not a scientist. Scientific evidence in the record establishes that "[t]he most important factor concerning timing of dosing and effectiveness is the interval between the first dose and unprotected intercourse," and that "[i]t is [] unlikely that the effectiveness of Plan B will be reduced if the second tablet is taken 6 to 18 hours, instead of exactly 12 hours, after the first dose." Medical Officer's Safety Rev. of SNDA at T-30799 (March 25, 2004), Case No. 05-cv-366, Doc. No. 235-3; *see also* Raymond Decl. ¶ 36. Yet the regime currently in place affects the most significant factor in terms of effectiveness of the product because it increases the delay between sexual intercourse and the first dose (the only dose in the case of Plan B One-Step).

Moreover, the two-pill actual use study submitted with the original Plan B SNDA demonstrated that "[t]here was excellent compliance with the labeled dosing regimen among subjects < 18 yr. of age. Compliance was at least as good as that in the subjects 18 yr. and older." Medical Officer's Safety Rev. of SNDA at T-30800 (March 25, 2004), Case No. 05-cv-366, Doc. No. 235-3. Although it is clear that the second pill need not be taken exactly 12 hours after the first in order for the drug to remain effective, compliance with this direction was nonetheless high. "Evaluation of the adolescents who did not take their second dose at exactly 12 hours revealed that nearly all took it within minutes of the 12 hour time point. There was one outlier that took the second dose 2 hours late." Deputy Div. Dir. Summ. Rev. of New Drug Application at T-30840, Case No. 05-cv-366, Doc. No. 235-4. Indeed, an FDA medical reviewer, in describing the results of the Plan B actual use study, concluded that "the timing of 1st and 2nd dose in the [actual use study] did not vary based on age." Addendum to Div. Dir. Memo at T-30749, Case No. 05-cv-366, Doc. No. 235-3. Nor did the actual use study support the argument that intervention by a health care provider, such as a pharmacist or doctor, impacts the timing of the second dose. Deputy Div. Dir. Summ. Rev. at T-30840-41, Case No. 05-cv-366, Doc. No. 235-4.[11]

In sum, the Citizen Petition denial was inevitable after the Secretary ordered Commissioner Hamburg to deny the Plan B One-Step SNDA. Because the Secretary's action was politically motivated, scientifically unjustified, and contrary to agency precedent, it cannot provide a basis to sustain the denial of the Citizen Petition. The Citizen Petition Denial Letter, which came five days after the denial of the Plan B One-Step SNDA, was clearly prompted by

[11] The results of these studies are not surprising, since, as Dr. Leonard-Segal observed, "[r]eliance upon the product label to result in appropriate use is consistent with the tenet that the Agency has applied in the past and continues to apply when determining whether or not a product can be over-the-counter. It is an approach consistent with the regulations." Summary Review at 28.

the Secretary's action, despite the FDA's fanciful effort to make it appear that it undertook an independent review of the Citizen Petition. Nevertheless, even considering the Citizen Petition Denial Letter in isolation, the agency's decision cannot withstand any degree of scrutiny, not only because of its unexplained failure to follow the FDA policies discussed above but also because of its disregard for the scientific evidence that the FDA had before it. Because the defendants argue that I cannot rely on the studies discussed above in reviewing the denial of the Citizen Petition, I now turn to that issue.

E. Proper Record on Review

1. The Actual Use and Label Comprehension Studies

The defendants argue that the actual use and label comprehension studies submitted with the Plan B One-Step switch application could not have been considered by the FDA in its review of the Citizen Petition and may not be considered here in my review of the Citizen Petition denial. They make this argument even though the very reason the FDA gave for denying the Citizen Petition was the lack of age-specific data, *as compared to* that submitted with the Plan B One-Step SNDA. Indeed, the FDA expressly acknowledged that it delayed consideration of the Citizen Petition for three years because it anticipated that the Plan B One-Step studies would be relevant to its reconsideration of the Citizen Petition. Thus, it wrote that "[w]hether actual use and label comprehension data were needed for approval of the nonprescription use of Plan B One-Step is *directly relevant* to whether those data were needed for the same approval for Plan B *because of the similarities between the products* and [because of] the data that the sponsor had developed to support the OTC approval of the products." Citizen Petition Denial Letter at 2 (emphasis added).

While it is difficult to understand why the Citizen Petition was not judged on the basis of the materials submitted in support of it instead of being compared to those materials submitted in support of a separate application by the Plan B One-Step sponsor that was denied, the FDA's consideration of these studies in evaluating the Citizen Petition is the beginning and the end of the argument that those studies cannot be considered. An even more significant fact, which the defendants ignore, is that the Administrative Record filed in this case does in fact contain a detailed PowerPoint summary of the most compelling details on the actual use study submitted in support of the Plan B One-Step application. Admin. R. at 598-619.

This leaves the FDA with an argument that the use of the studies submitted by the Plan B One-Step sponsor, Teva Women's Health, Inc. ("Teva"), would deprive Teva of the right to three years of exclusive marketing of Plan B One-Step, to which it would have been entitled under the FDCA. *See* 21 U.S.C. § 355(c)(3)(E)(iv) & 355(j)(5)(F)(iv). This exclusivity could only have followed if Teva's application for over-the-counter access had been granted by the FDA based on a finding by the FDA that those studies were "essential" to the approval. Defs.' Resp. to Order to Show Cause at 24, Case No. 12-cv-763, Doc. No. 23. The purpose underlying this exclusivity provision, according to both the FDA and Teva, is "to encourage and reward drug manufacturers who devote the time and expense to clinical trials necessary to approve changes to a drug product." *Id.*; Teva's Proposed Mem. Of Law in Resp. to Order to Show Cause at 11, Case No. 12-cv-763, Doc. No. 22-2.

The FDA conceded that the actual use and label studies submitted by Teva were sufficient to justify a complete over-the-counter switch, although it suggested that the label comprehension study was not essential. Thus, the Citizen Petition Denial Letter stated that, "[a]s part of the anticipated approval, FDA was prepared to determine that the clinical [actual use]

study that Teva submitted for Plan B One-Step was essential to any approval of non-prescription marketing of the product and thus grant 3-years of exclusivity." Citizen Petition Denial Letter at 9. Nevertheless, Teva was not granted exclusivity because, as the Citizen Petition Denial Letter explained, the "FDA's final determination on exclusivity was not made because FDA determines whether to grant exclusivity *after product approval*." *Id.* at 9 n.4 (emphasis added). Because Teva's application was denied, it does not enjoy any exclusivity. Thus, the policy justification underlying the exclusivity provisions of the FDCA does not apply here. Teva has chosen not to appeal the denial of the Plan B One-Step SNDA; rather, it claims to be involved in "active dialogue with the FDA right now," and it has acquiesced in the suggestion that it could still appeal if the FDA should adhere to its position. Apr. 27, 2012 Hr'g Tr. at 22:9-10, Case No. 12-cv-763, Doc. No. 84. Nor is Teva currently marketing Plan B One-Step for universal over-the-counter access. Under these circumstances, Teva's position will not be affected whether the case is decided in favor of the FDA or the plaintiffs—in either case, it will not enjoy exclusivity. There is simply no reason in law or policy why the studies submitted by Teva should not be considered in my review of the Citizen Petition denial.

The defendants' final arrow in their effort to invoke Teva's commercial interests to prevent reliance on the Plan B One-Step studies turns on the fact that Teva has never given its permission for the Citizen Petition proponents to use its studies. Specifically, the defendants argue that "a sponsor's clinical studies cannot be applied to support the approval of another manufacturer's drug product unless the drug sponsor grants a 'right of reference' to those studies." Defs.' Mem. in Opp. to Summ. J. at 34 n.9, Case No. 12-cv-763, Doc. No. 37. They cite one statute, 21 U.S.C. § 355, and one regulation, 21 C.F.R. § 314.3. I decline to consider this argument, upon which even Teva itself does not rely, because it was advanced in a single

footnote, it relied on a 20,000+ word statutory section with numerous parts and subparts without any pincite to the relevant language, and the footnote did not in any way develop the legal argument to which the defendants allude. Nor did the regulation on which they rely. "Judges are not like pigs, hunting for truffles buried in briefs." *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991) (per curiam). It is not my job, in a case in which numerous briefs and motions have been filed, to "scour[] through footnotes in search of some possibly meritorious point that counsel did not consider of sufficient importance to [develop or] include as part of the argument." *United States v. Restrepo*, 986 F.2d 1462, 1463 (2d Cir. 1993).

2. The Declarations Submitted in Support of Plaintiffs' Summary Judgment Motion

In an effort to restrict my consideration of declarations submitted by the plaintiffs in the current proceeding, the defendants invoke a rule which they claim precluded their own consideration of materials that were not part of the Citizen Petition docket. The only regulation cited by the defendants is 21 C.F.R. § 10.20(c), which provides that "[i]nformation referred to or relied upon in a submission is to be included in full and may not be incorporated by reference, unless previously submitted in the same proceeding." This is no more than a stylistic rule which says that any material explicitly relied on in a submission must be included in full. It does not address the issue of what information may be considered by the agency. Indeed, in the Citizen Petition Denial Letter, the FDA itself considered the studies submitted in support of the Plan B One-Step SNDA, although they were not part of the Citizen Petition docket. Moreover, after advising the Citizen Petition proponents that "[n]either your petition nor any of the public comments to the docket contain sufficient data to satisfy the statutory requirements for FDA to remove the Rx requirements for Plan B for women under the age of 17," it observed that, "[i]n addition, FDA does not have any data from other sources that would be sufficient to support such

a switch." Citizen Petition Denial Letter at 10. This clearly indicates that the FDA did have the discretion to consider evidence outside the Citizen Petition docket.

A brief discussion of the declarations demonstrates the extent to which the FDA abused its discretion when it failed to consider evidence to which it had access even though it was not in the Citizen Petition docket. The plaintiffs submitted five declarations. Of these, two were by scientists who participated in the studies submitted in support of the Plan B One-Step SNDA. These declarations contain summaries of the studies of which the FDA was aware and which the FDA concluded were sufficient to support "the safe and effective [over-the-counter] use of Plan B One-Step in women under age 17," the details of one of which were included in the Administrative Record. Citizen Petition Denial Letter at 9-10. This consideration aside, at least one of the declarations exposed evidence of the agency's bad faith. Specifically, those declarations disclosed the fact that the FDA itself had excused the necessity for study data on women under the age of 13. Notwithstanding the lengthy discussion of the SNDA review process contained in the Citizen Petition Denial Letter, neither I nor the petitioners would have known that the Secretary had, in effect, directed the FDA to deny the Plan B One-Step SNDA because it lacked information that the FDA told the sponsor did not have to be included.

The third declaration was by Dr. Miriam Cremer. The declaration called my attention to a highly significant label comprehension study involving girls between the ages of 12 and 17 and a prototype two-pill emergency contraceptive label. Moreover, it too disclosed evidence of bad faith. Specifically, the declaration alleged that the FDA had asked for a copy of Dr. Cremer's study and that she had provided it. It was only after I asked whether that statement was true that the defendants admitted that the FDA had itself discovered that study as part of a literature review and had considered it during the SNDA review process. Again, although the Citizen

Petition Denial Letter discussed the studies submitted with the Plan B One-Step SNDA, it omitted any mention of Dr. Cremer's study, which was as compelling as the label comprehension study submitted with the Plan B One-Step SNDA.

The fourth declaration is that of Mary Pendergast, a lawyer who was formerly employed as an FDA official and who was intimately familiar with the manner in which the agency operated. Only because of that declaration did I learn that the Secretary of Health and Human Services had delegated all of her authority to the Commissioner of the FDA under 21 U.S.C. § 301 *et seq.*, which includes the relevant statutes relating to new drug applications and switch applications to over-the-counter status, subject to two minor exceptions not relevant here. This delegation of authority is highly relevant to the discussion of the power of the Secretary and the scope of review. Nevertheless, the defendants failed to disclose it. Moreover, although Ms. Pendergast's submission is in the form of a declaration, it is more easily characterized as an amicus brief, and I treat it as such; I rely on it only for the information to which it drew my attention and of which I could take judicial notice in any event.

The fifth declaration is that of Dr. Tracey Wilkinson, who described the practical difficulties faced by adolescents seeking contraceptives from pharmacies. The declaration does not affect my decision in this case. I merely discuss her research to illustrate the obstructions to obtaining emergency contraception under the current regime. My decision, however, would be the same even without reference to the real-life consequences of the Secretary's conduct. Her decision with respect to the Plan B One-Step SNDA, which dictated the denial of the Citizen Petition, was arbitrary, capricious, and unreasonable for the reasons I have already outlined and do not repeat.

3. Administrative Record Rule

The last rule the FDA relies on to preclude consideration of documents unhelpful to its position is the rule that a reviewing court must judge the propriety of administrative agency action "by the grounds invoked by the agency." *Secs. Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194, 196 (1947). "The task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985). "Generally, a court reviewing an agency decision is confined to the administrative record compiled by that agency when it made the decision." *Nat'l Audubon Soc'y v. Hoffman*, 132 F.3d 7, 14 (2d Cir. 1997) (citing *Fla. Power*, 470 U.S. at 743-44). The rationale behind the "record rule" is that a reviewing court, "in dealing with a determination or judgment which an administrative agency alone is authorized to make," *Chenery*, 332 U.S. at 196, should not conduct a *de novo* trial, review materials not before the agency when the decision was made, or substitute its opinion for that of the agency.

Nevertheless, the law is clear that a reviewing court may consider extra-record materials in certain circumstances. *See Nat'l Audubon*, 132 F.3d at 14-15. Indeed, "a strong showing of bad faith or improper behavior" may justify supplementing the record. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420 (1971). Thus, when the agency action cannot be adequately explained in the record it compiled, the court's consideration of evidence outside the agency's "administrative record" is not only warranted, *Esch v. Yeutter*, 876 F.2d 976, 991 (D.C. Cir. 1989), but necessary to a meaningful judicial review of the agency's action. *See Asarco, Inc. v. EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980) (Agency record may be supplemented when

additional information "fully explicate[s] . . . [the agency']s course of conduct or grounds of decision.").

When this issue arose in prior proceedings in this case, I observed in my 2009 opinion that:

> None of the dangers the record rule is designed to prevent are implicated by consideration of the materials in the administrative record for the SNDAs submitted by the Plan B sponsor because these materials were "before the agency when the decision was made" and because the FDA itself relied on those materials when it denied the Citizen Petition. Indeed, from the very beginning, FDA staff acknowledged that the Plan B sponsor would work with the FDA to address any concerns raised by the Citizen Petition. Def.'s Ex. 3, Case No. 05-cv-366, Doc. No. 248-5 at T-30023. Moreover, no meaningful review of the denial of the Citizen Petition would be possible without a review of the administrative record for the SNDAs because the FDA understood the issues presented by the SNDAs and Citizen Petition to be one and the same.

Tummino, 603 F. Supp. 2d at 543.

In sum, I held in 2009 that the complete "record" for the FDA's decision regarding the Citizen Petition included its own administrative record for both the Citizen Petition and the SNDAs. Moreover, to the extent that this was not by itself a sufficient basis to do so, I also concluded that there was a "showing of bad faith or improper behavior" that justified supplementing the record, and that consideration of evidence outside the agency's administrative record was necessary to meaningful judicial review of the agency's actions. Then, based on the entire record before me, I vacated the FDA's denial of the Citizen Petition and ordered it to make Plan B available to 17-year-olds because the same evidence relied on by the agency to make the drug available to 18-year-olds applied equally to 17-year-olds, and I remanded for reconsideration the denial of the application to make Plan B available to younger adolescents. The FDA acquiesced in that ruling.

The same reasons that justified my consideration of materials outside the administrative record in 2009 apply equally here, including a strong showing of bad faith and improper political influence. I have already discussed the declarations and the studies in the preceding sections, and I do not repeat that discussion here. Thus, even absent a showing of bad faith, the materials were relevant for the limited reasons I relied on them and because they came within the exceptions to the record rule I have already discussed. Indeed, the defendants have included documents from the Plan B One-Step SNDA review process in the Administrative Record for the Citizen Petition, conceding to some extent the relevance of the SNDA proceeding. Again, one of the most significant of those documents was a presentation containing details of the actual use study submitted in support of the SDNA.

The only document I have not yet discussed is the Summary Review for Regulatory Action, which Secretary Sebelius said she reviewed prior to issuing her directive to the FDA to reject the Plan B One-Step SNDA. This document is properly considered here because the Secretary's decision dictated the denial of the Citizen Petition, notwithstanding the smoke and mirrors in the Citizen Petition Denial Letter, and I cannot effectively review the Citizen Petition denial without reviewing the Secretary's decision. In any event, I have only relied on the parts of this document that describe the policies and practices of the FDA, which are necessary to a meaningful judicial review of the agency's action.

III. CONCLUSION

The decisions of the Secretary with respect to Plan B One-Step and that of the FDA with respect to the Citizen Petition, which it had no choice but to deny, were arbitrary, capricious, and unreasonable. I decline to direct a remedy comparable to that which I directed in my 2009 opinion, such as directing that emergency contraception be made available without a prescription

but with the current point-of-sale restrictions to women whom studies have demonstrated are capable of understanding the label and using the product appropriately. As I have previously observed, the obstructions in the path of those adolescents in obtaining levonorgestrel-based emergency contraceptives under the current behind-the-counter regime have the practical effect of making the contraceptives unavailable without a doctor's prescription. Consequently, the decision of the FDA denying the Citizen Petition is reversed, and the case is remanded to the FDA with the instruction to grant the Citizen Petition and make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days. On remand, the FDA may determine whether any new labeling is reasonably necessary. Moreover, if the FDA actually believes there is any significant difference between the one- and two-pill products, it may limit its over-the-counter approval to the one-pill product.

I do not grant the application of the FDA to remand for the commencement of administrative rulemaking proceedings. In my previous opinion, I described the means by which the FDA may switch a drug to over-the-counter status. *Tummino*, 603 F. Supp. 2d at 525. I described two methods by which the FDA could change a drug's status: first, by promulgating a regulation through rulemaking initiated by either the Commissioner herself or a citizen petition, or by approving a drug sponsor's request for an over-the-counter switch. I observed, "[u]nlike the first mechanism, this process does not require rulemaking." *Id.* On further review, I believe that no statute or regulation requires the FDA to engage in administrative rulemaking upon approval of a citizen petition or *sua sponte* reconsideration of a drug's prescription-only status. The relevant statute, 21 U.S.C. § 353(b)(3), provides that "[t]he Secretary may by regulation remove . . . drugs from [prescription] requirements . . . when such requirements are not necessary

for the protection of the public health." The statute does not require the agency to act by regulation, but provides only that it *may* do so.

Moreover, the regulations explicating over-the-counter switch procedures do not require rulemaking for changes initiated through a citizen petition or by the Commissioner herself; indeed, there is no suggestion that over-the-counter switches are treated differently based on the process by which they are initiated. 21 C.F.R. § 10.30, which deals with citizen petitions, specifically provides that the Commissioner "may grant or deny such a [citizen] petition, in whole or in part, and *may grant such other relief or take other action as the petition warrants*" (emphasis added). The section does not say that agency rulemaking is required prior to agency action on a citizen petition. Indeed, the Citizen Petition in this case does not seek rulemaking; it merely requests "that the [FDA] switch [Plan B and its generics] from prescription to over-the-counter (OTC) status." Citizen Petition at 1, Case No. 05-cv-366, Doc. No. 316-9. In addition, although the Citizen Petition requested a complete switch when it was filed twelve years ago, because Plan B was not yet available on a non-prescription basis to any consumer, this is not the case any longer. The relief sought by the Citizen Petition in light of present circumstances is limited to a partial over-the-counter switch for females under 17. No previous modifications of Plan B's over-the-counter status required rulemaking, including the expansion of over-the-counter access to 18-year-olds and, later, 17-year-olds as directed by my 2009 remand order.

Nor do the regulations distinguish between SNDAs, Commissioner-initiated agency action, and citizen petitions. 21 C.F.R. § 310.200, titled "Prescription-exemption procedure," states: "A proposal to exempt a drug from the prescription dispensing requirements of [the FDCA] may be initiated by the Commissioner or by any interested person. Any interested person may file a petition seeking such exemption, which petition may be pursuant to part 10 of

this chapter [citizen petitions], or in the form of a supplement to an approved new drug application." The regulations do not say that these three means of initiating rulemaking require different responses from the FDA. And the defendants have not proffered any other support for the proposition that the grant of a Citizen Petition would merely result in the initiation of rulemaking other than the language from my previous decision.

Finally, even if the defendants' arguments would be sufficient to carry the day in the run-of-the-mill case, the bad faith that has permeated consideration of the Citizen Petition, not to speak of the Plan B sponsor's applications, should rule out such relief here. More than twelve years have passed since the Citizen Petition was filed and eight years since this lawsuit commenced. The FDA has engaged in intolerable delays in processing the petition. Indeed, it could accurately be described as an administrative agency filibuster. Moreover, one of the devices the FDA has employed to stall proceedings was to seek public comment on whether or not it needed to engage in rulemaking in order to adopt an age-restricted marketing regime. After eating up eleven months, 47,000 public comments, and hundreds of thousands, if not millions, of dollars, it decided that it did not need rulemaking after all. The plaintiffs should not be forced to endure, nor should the agency's misconduct be rewarded by, an exercise that permits the FDA to engage in further delay and obstruction.

REVERSED and REMANDED.

SO ORDERED.

Brooklyn, New York
April 4, 2013

Edward R. Korman

Edward R. Korman
Senior United States District Judge